DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 26, 2010 has been entered.

2. Applicants' arguments, filed February 26, 2010, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Rejoinder

3. Applicants' request for rejoinder is not granted. The claims must be in condition for allowance in order for rejoinder to be considered. As shown below, the claims are not in condition for allowance.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1 – 6, 8 – 12 and 32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 21, 3 and 34 – 36 of copending Application No. 10/485,456 in view of Kelley et al (Lipids 1998).

The claims of '456 recite administration of amounts of arachidonic acid (AA) ranging from 0.01 – 20 g to subjects. The outcome of this method is the treatment or amelioration of decreased learning ability, cognitive ability or memory caused by decreased brain function.

The claims of '456 do not recite "healthy adult persons" as the subjects being treated as recited in the instant claims.

Kelley et al. discloses that 200 mg or 1.5 g of AA is included in the diets fed to healthy adult males ("Subject, protocols, and diets" section, p – 125 – 126).

It would have been obvious to one of ordinary skill in the art to practice the method of '456 of healthy adult persons as Kelly et al. discloses that such amounts of AA can be administered to healthy adult persons. The amounts of AA administered in '456 overlap with the range of at least 200 mg recited in the instant claims. Overlapping ranges are *prima facie* obvious (see MPEP 2144.05). Among the effects stated in the

claims of '456 is ameliorating (e.g., improving) cognitive ability as is stated in the preamble of the instant claims.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 112 – 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1 – 6, 8 – 19 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The specification as filed does not support a daily intake for arachidonic acid of at least 200 mg. The portion of the specification cited by Applicants indicates that 200 mg (0.2 g) is the upper limit of arachidonic intake from food in the Kansai region of Japan. However, the sentences that immediately follow indicate the contemplated AA intake ranges from 0.001 – 20 g, 0.01 – 10 g, 0.05 – 5 g and 0.1 – 2 g. The contemplated intakes are narrower than the limitation of "at least 200 mg".

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1 and 13 – 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelley et al. (Lipids 1998).

Kelley et al. discloses the administration of a basal diet providing 200 mg of arachidonic acid (AA) and a diet supplemented with AA (1.5 g/d) to ten healthy men ranging in age from 20 – 38 years of age, which reads of the healthy adult person patient population of the instant claims ("Subject, protocols, and diets" section, p – 125 – 126). The diet administered reads on a food composition.

As amended, the instant claims state that an amount sufficient to prevent decline of, improve, or enhance cognitive ability is represented by a daily AA intake of at least 200 mg. As Kelley et al. teaches administration of such amounts to the same patient population as the instant claims (healthy adult persons), the same effects must occur. Therefore, the cited prior art anticipates the instant claims as the same method applied to the same patient population must have the same outcome of preventing the decline of, improving or enhancing cognitive abilities such as those exemplified in claims 13 – 19.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 2, 8, 9, 13 – 19 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelley et al. (Lipids 1998) in view of Barclay (US 5,583,019).

Kelley et al. discloses the administration of a basal diet providing 200 mg of arachidonic acid (AA) and a diet supplemented with AA (1.5 g/d) to ten healthy men ranging in age from 20 – 38 years of age, which reads of the healthy adult person patient population of the instant claims. The diet administered reads on a food composition.

Kelley et al. does not disclose the eicosapentaenoic acid (EPA) content of the diet.

Barclay discloses that it is preferred that the AA containing oils contain little or no other long chain highly unsaturated fatty acids such as EPA because some of these fatty acids can interfere with AA utilization and/or inhibit blending of the oils to achieve the appropriate ratio of fatty acid to match breast milk or other desired application (col 1, ln 37 – 46). The compositions can be administered to infants or adults such as pregnant mothers (col 9, ln 32 – 34). Commercially feasible amounts of AA are produced from a microbe belonging to the genus *Mortierella* (col 2, ln 35 - 49). As the fatty acids are contained in the neutral oil fraction, the AA is contained in triglycerides (col 15, ln 23 – 24; Table 8).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to administer a diet high in AA and containing little or no EPA to the healthy adult males as in Kelley et al. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected

success because Barclay discloses that other highly unsaturated fatty acids such as EPA can interfere with the beneficial effects of AA and/or subsequent processing and blending steps with the AA containing oil.

It also would have been obvious to provide the AA in the form of triglycerides as Barclay discloses that economically feasible amounts of AA are produced as triglycerides in extract obtained from *Mortierella*. The fatty acids do not need to be administered in the free fatty acid form to have beneficial effects and the disclosure of Barclay provides an economically feasible source of the important polyunsaturated fatty acid AA.

14. Claims 1 - 6, 8 - 19 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelley et al. and Barclay as applied to claims 1, 2, 8, 9, 13 – 19 and 32 above, further in view of JP 08-214891 (JP'481).

As discussed in greater detail above, Kelley et al. and Barclay disclose the administration of 200 mg of 1.5 g of AA to healthy adult males. Extracts of *Mortierella* provide an economically feasible source of AA in the form of triglycerides. EPA can interfere with the activity and/or subsequent processing of the AA containing oil so compositions with little or no EPA can be desirable. As the same composition is administered to the same patient population as recited in the instant claims, the same results must necessarily occur, such as the cognitive effects recited by the instant claims.

Neither reference discloses the location of AA in the triglycerides as required in claims 3 and 10, for example.

JP'891 discloses a method of making triglycerides that contain a high concentration of higher unsaturated fatty acids (LCPUFAs; ¶ [0001]). Positions 1 and 3 of the triglyceride are occupied by medium chain fatty acids, and the higher unsaturated fatty acid is at the 2 position, in a high concentration (¶ [0009]). Examples of medium chains fatty acids contain 6 – 12 carbon atoms, such as caprylic (8 carbons) or capric acid (10 carbons; ¶ [0011]). With a docosahexanoic acid at the 2 position, a reaction with an 8 carbon, medium chain fatty acid resulted in a concentration of the LCPUFA of about 30% (¶ [0027]). The higher unsaturated fatty acid can be arachidonic acid, docosa-hexaenoic and/or eicosapentaenoic acid (¶ [0011]). Preparation of these triglycerides allows for a higher concentration of the higher unsaturated fatty acids, which possess various bioactivities (¶ [0037]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use a triglyceride with medium-chain fatty acids bound at the 1 and 3 positions and AA bound at the 2 position. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success because JP'481 discloses that such triglycerides allow for higher concentrations of the higher unsaturated fatty acid (like AA) to be prepared. It is the higher fatty acids like AA which have the pharmacological effects and higher concentrations in the oil allow for lesser amount of the oil to be used to deliver the same

amount of the pharmacologically active AA or the deliver a higher dose of the pharmacologically active in the same volume.

15. Claims 1, 2, 6, 8 and 13 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (US 2002/0040058).

Kiliaan et al. discloses method for the prevention and/or treatment of vascular disorders and/or secondary disorders associated therewith like atherosclerosis, such as depression, by the oral administration of a composition comprising long chain polyunsaturated fatty acids (¶¶ [0080], [0030] – [0031]). This fraction may contain free omega-3 and omega-6 fatty acids, but the fatty acids are preferably bound to a suitable backbone, for instance in the form of a triglyceride or phospholipid (¶ [0036]). Preferred omega-6 LCPUFAs are AA and dihomogammalinolenic acid (DHGLA) in an amount of about one fourth the amount of EPA and DHA (¶ [0038]). The amounts of EPA and DHA are 20 – 2000 mg and 50 – 2000 mg DHA (¶ [0038]), leading to amounts of DHGLA and AA of 17.5 – 1000 mg, a range which overlaps with the range of the instant claims. Killian et al. discloses that in addition to treatment of vascular disorders, the method can also be used to prevent such disorders (¶ [0030]). When used in this preventative role, the patients would be healthy. Generally, vascular disorders and atherosclerosis are more likely to occur the older one gets, so adults would be a higher risk of developing these conditions and therefore a target population for administration of compositions to prevent these conditions from occurring.

Kiliaan et al. does not explicitly provide a dosage of at least 200 mg of AA to healthy adult persons.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to administer an AA containing compositions to healthy adults in order to prevent vascular disorders and/or secondary associated disorders. The person of ordinary skill in the art would have been motivated to make those modifications and reasonably would have expected success as Kiliaan et al. discloses that the compositions can be administered for the prevention of the particular conditions described, which indicates administration to healthy adults.

Overlapping ranges for the amount of AA administered is *prima facie* obvious (see MPEPE 2144.05). The amount of a specific active component in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results of prevention or treatment of the various conditions.

The source of the triglyceride, as stated in claim 8, is a product-by-process limitation whose patentability is determined by the product, not the process used to obtain the product. There is no evidence to indicate that the triglycerides obtained from microbes belonging to the genus *Mortierella* are different from the triglycerides in the used in the compositions of Kiliaan et al.

16. Claims 1, 2, 6, 8 and 13 – 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (US 2002/0040058) in view of Barclay (US 5,583,019). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed July 3, 2008 and March 2, 2009 and those set forth below.

Applicants traverse this rejection on the grounds that Kiliaan fails to disclose administration to a subject a daily intake of at least 200 mg. Barclay administers AA to infants, not healthy adult persons as claimed. Barclay does not teach the amount of AA to administer to infants.

These arguments are unpersuasive. Guidance as to the daily intake is provided by Kiliaan et al. which states that the amount of omega-6 LCPUFAs as AA and DHGLA should be one fourth the amount of EPA and DHA (¶ [0038]). The amounts of EPA and DHA are 20 – 2000 mg and 50 – 2000 mg DHA (¶ [0038]), leading to amounts of DHGLA and AA of 17.5 – 1000 mg, a range which overlaps with the range of the instant claims. As discussed in greater detail above, Kiliaan et al. discloses that the condition can be prevented by administration of the AA-containing compositions, which requires administration to a healthy adult person. Contrary to Applicants assertion, Barclay also discloses that the AA can be used to treat adults, in particular pregnant mothers (col 9, ln 32 - 39). Pregnant mothers also read on the patient population of healthy adults encompassed by the instant claims.

17. Claims 1 – 6 and 8 – 19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kiliaan et al. (US 2002/0040058) in view of JP 08-214891 (JP'481). This rejection is MAINTAINED for the reasons of record set forth in the Office Actions mailed July 3, 2008 and March 2, 2009 and those set forth below.

Applicant traverses this rejection on the grounds that Kiliaan fails to disclose administration to a subject a daily intake of at least 200 mg. '891 is directed to manufacturing concentrated fats and oils with triglycerides with a higher unsaturated fatty acid content. There is no issue on the record whether the artisan knew how to make such compositions. Obviousness cannot be shown merely by showing that a known composition could have been modified by routine experimentation or solely on the expectation of success. It must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that would result in the claimed invention. '891 does not motivate modifying Kiliaan to deliver the claimed daily amount of AA to a healthy adult person nor to administer AA to prevent decline of, improve or enhance cognitive responses of a healthy adult person.

These arguments are unpersuasive. Guidance as to the daily intake is provided by Kiliaan et al. which states that the amount of omega-6 LCPUFAs as AA and DHGLA should be one fourth the amount of EPA and DHA (¶ [0038]). The amounts of EPA and DHA are 20 – 2000 mg and 50 – 2000 mg DHA (¶ [0038]), leading to amounts of DHGLA and AA of 17.5 – 1000 mg, a range which overlaps with the range of the instant claims. As discussed in greater detail above, Kiliaan et al. discloses that the condition can be prevented by administration of the AA-containing compositions, which requires

administration to a healthy adult person. Therefore, '891 need not motivate one to administer the claimed amounts as those teachings are found in Kiliaan et al.

As amended, the instant claims state that an amount sufficient to prevent decline of, improve, or enhance cognitive ability is represented by a daily AA intake of at least 200 mg. As the combined prior teaches administration of such amounts to the same patient population as the instant claims (healthy adult persons), the same effects must occur. Therefore, the cited prior art renders obvious the instant claims as the same method applied to the same patient population must have the same outcome, preventing the decline of, improving or enhancing cognitive abilities such as those exemplified in claims 13 – 19.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
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